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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,247	02/06/2004	Siegfried Noetzel	RDID 03026 US (WP21397)	9104

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,247	NOETZEL ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2007 and 15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 23-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 23-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/26/04, 10/10/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election without traverse of Group I, claims 1-10 and 23-24 in the reply filed on October 10, 2007 is acknowledged.

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising". Correction is required. See MPEP § 608.01(b).

5. Claims 1-10 and 23-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since it is not clear that the same blood sample applied to the application site of the substrate body flows both to the dilution channel and the sample channel so that the "blood sample aliquot to be diluted" recited on line 6 of claim 1 is the same as the blood sample in the dilution channel whose corpuscular blood components are separated. Claim 1 lacks structural cooperation between the application site of the substrate body and both the dilution channel and the sample channel. How are these physical components of the apparatus

connected together? As claim 1 is presently recited, the dilution channel can contain a different blood sample than the sample channel since a branching junction channel from the application site leading to both of the dilution and sample channels is not positively recited. Claim 1 is also indefinite since it is not clear whether the "blood sample aliquot to be diluted" is a whole blood sample or just some portion of a blood sample (i.e. a particular cell portion such as red blood cells).

On line 2 of claim 2, the phrase "the sample flow" lacks antecedent basis. Claim 2 is indefinite since it is not clear where the junction is located in the apparatus. At the application site of the substrate body?

On line 3 of claim 3, the phrase "the subflows of the blood sample" lacks antecedent basis since claim 1 does not positively recite a blood sample flowing from the application site into two different subflows, one leading to the dilution channel and the other leading to the sample channel.

In claims 4 and 5, the phrase "the flow rate" lacks antecedent basis.

In claim 8, the phrase "the diluted blood sample" lacks antecedent basis since claim 1 never positively recites a blood sample that has been diluted. Claim 1 only positively recites that a blood sample meets the dilution channel at a mixing site. See this same problem in claim 10.

Claim 9 is indefinite since it is not clear where in the apparatus the first and second analytical channels are located in relation to the application site, the dilution channel and the sample channel. Structural cooperation among these physical components of the apparatus is missing.

Claim 23 is indefinite since it is not clear where in the analytical test element the liquid components of a blood sample are obtained. Are the liquid components obtained in the microfluidic channel structure, in the application site or in the at least one analytical site? In addition, it is also unclear where the liquid components are added to "a portion of the blood sample to be analyzed". It is unclear where in the analytical test element the dilution of a blood sample takes place. It is also unclear whether the "portion of the blood sample to be analyzed" is the same as the blood sample whose liquid components are obtained somewhere in the device. It is also unclear whether the "portion of the blood sample to be analyzed" is a whole blood sample or just some portion of a blood sample (i.e. a particular cell portion such as red blood cells).

On lines 1-2 of claim 24, the phrase "the starting material" lacks antecedent basis. On line 3 of claim 24, the phrase "the subflow that has been depleted of cell components in the dilution channel" lacks antecedent basis since it was not previously recited that this occurs in the dilution channel. The location of the mixing site in claim 24 is also unclear and vague. Is the mixing site located downstream of the sample and dilution channel?

In claim 27, the phrase "the wall sections" should be changed to --the wall structures-- so as to use the same terminology as used in claim 26.

On line 2 of claim 30, the phrase "can be" should be changed to --is-- so that the limitation is positively recited.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 6-7 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Gordon et al (US 7,087,203).

Gordon et al teach of a microfluidic bio-disc and method for analyzing blood samples. In the embodiment depicted in Figure 14, a whole blood sample is loaded directly onto a bio-disc at an application site that leads directly to a dilution channel containing cell separation means 250. See the circle depicted as the application site immediately before separation means 250 in Figure 14 of Gordon et al. The cell separation means 250 serves to separate blood cells from plasma when the bio-disc is spun at a first speed in a centrifuge. The spinning of the bio-disc serves to move the whole blood sample through the microfilter 250 designed to separate out red blood cells, white blood cells and platelets from plasma. Plasma is then moved to a mixing chamber 252 by spinning the disc at a second speed higher than the first speed. A blood cell sample is added to a sample channel in the microfluidic channel structure of the bio-disc at entry port 256. The sample channel leads into the mixing chamber 252 so that the blood cell sample applied at

port 256 combines with the plasma separated in the dilution channel. Mixing of the plasma and blood cell sample in the mixing chamber 252 is accomplished by spinning the disc at least once one-half a rotation counter clockwise and then clockwise one-half a rotation. The sample is allowed to incubate in the mixing chamber for a sufficient time, and then the blood cell sample diluted with plasma is moved to a capture chamber 254 where the diluted blood cell sample is analyzed. See lines 9-54 in column 20 and Figure 14 of Gordon et al. Since instant claims 1, 6-7 and 23 do **not** specify that the same whole blood sample is passed through both the dilution channel and the sample channel from a common application site thus resulting in a whole blood sample being diluted with its own plasma, and does **not** specify that the blood sample aliquot to be diluted is a whole blood sample, the limitations taught for the bio-disc of Gordon et al serve to anticipate claims 1, 6-7 and 23 since the bio-disc comprises a microfluidic channel structure having an application site (i.e. 256), an analytical site (i.e. 254), a dilution channel containing a separation means (250) and a sample channel that conveys a blood sample to be diluted (i.e. the channel leading from application site 256).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 4-5 and 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al (US 7,087,203) in view of Macho et al (WO 01/24931, submitted in the Information Disclosure Statement filed on July 26, 2004). For a teaching of Gordon et al, see previous paragraphs in this Office action. Gordon et al fail to teach of the flow rates through the dilution channel and sample channel relative to one another, fail to teach that capillary action with various wall structures and valve elements is used to transport the blood sample through the microfluidic channel structure of the bio-disc, and fail to teach that the microfilter separation means in the dilution channel is a glass fiber fleece or microporous filter matrix.

Macho et al teach of a capillary device for separating undesired components such as blood cells from a liquid sample such as whole blood. The device comprises a first and second capillary zone, which are in contact with one another to enable liquid transfer. The first capillary zone contains a capillary-active porous matrix material that serves to capture corpuscular blood components therein. The porous matrix material is a glass fiber fleece. The second capillary zone comprises one or several capillary channels or gaps which are partially overlapped by the porous matrix material of the first capillary zone. The second capillary zone can contain wall structures in the form of thin lines or minute projections. The capillary channels or gaps in the second capillary zone can be partially hydrophilized to form valve elements. See the abstract and claims in Macho et al.

Based upon the combination of Gordon et al and Macho et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use capillary action to transport the blood sample through the microfluidic channel structure of the bio-disc taught by Gordon et al since Macho et al disclose that the use of capillary action with porous matrix materials, wall structures and hydrophilized valve elements serve to effectively transport a blood sample through an analytical test element in order to separate blood cells from a whole blood sample, which is the purpose of the bio-disc taught in the embodiment depicted in Figure 14 of Gordon et al. Thus, claims 25-30 would have been obvious because the use of capillary action in an analytical test device to separate blood cells from a whole blood sample was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of Macho et al. It also would have been obvious to one of ordinary skill in the art to use a glass fiber fleece as the microfilter separation means in the bio-disc taught by Gordon et al since Macho et al disclose the use of this material as an effective and efficient filter means for separating blood cells from a whole blood sample in order to obtain plasma, which is the purpose of the bio-disc taught by Gordon et al. It also would have been obvious to one of ordinary skill in the art to adjust the flow rates of the blood sample through the dilution channel and sample channel in the bio-disc taught by Gordon et al to the rates recited in instant claims 4 and 5 since flow rate is a result effective parameter that can be varied experimentally depending upon an intended use and a desired outcome of a device.

12. Claims 2-3, 8-10 and 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record

teaches or fairly suggests an analytical test element for analyzing a whole blood sample that comprises a single application site for a whole blood sample, a junction located proximate to the application site for dividing the blood sample into two parallel subflows, wherein one subflow flows to a dilution channel containing a separation means for retaining corpuscular blood components and another subflow flows to a sample channel that conveys the whole blood sample, and a mixing site located downstream of the dilution and sample channels where plasma separated out in the dilution channel combines with the whole blood sample from the sample channel to dilute the whole blood sample with its own plasma at the mixing site.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Bhullar et al (US 6,406,672 and 6,319,719) who teach of a device for separating plasma from blood cells; Hoshino et al and Neumann et al who teach of methods for diluting a whole blood sample with its own plasma; and Shartle et al who teach of a microfluidic device containing microfluidic channels therein and a filter at the entrance port for separating blood cells from the sample.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

December 5, 2007

Maureen M. Wallenhorst
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